

Title 64 Series 7

Department of Health and Human Resources

Bureau for Public Health

REPORTABLE DISEASES, EVENTS AND CONDITIONS

Summary of the Public Comments:

The Department of Health and Human Resources (the "Department") notes that the comments received were concerned primarily with technical improvements and do not change the overall operation of the rule. However, in an effort to clarify the electronic reporting requirements for laboratories, modifications in addition to specific comments have been made. Because this rule is unique in that diseases, conditions and events that are required to be reported may be modified by Order of the State Health Officer, outstanding orders associated with this rule were included in these modifications to the rule. All of the outstanding Orders are publicly available and filed with this rule on the Secretary of State's website.

General Comment

The comment was received that it is burdensome for laboratories to be required to report results electronically.

Response

The Department has reviewed the comment, and no changes were made to the rule. Especially during a pandemic such as COVID-19, the receipt of real time accurate laboratory results by the Bureau for Public Health (the "Bureau") is essential for the preservation of life and health.

Without electronic reporting, Bureau personnel must receive laboratory results in paper form and manually enter those results into a disease surveillance database, a process that is labor intensive, time consuming, and can result in data transmission errors. Most every state in the United States requires electronic laboratory reporting. All laboratories in West Virginia are presently required to report electronically by Order of the State Health Officer. The Department has dedicated state resources in an effort to bring all laboratories in West Virginia into compliance with the electronic reporting requirement.

Section 1 – General.

Comment

1.6. The current language refers to the "administrators of the West Virginia Health Information Network (WVHIN)." The WVHIN requests that "administrators of" be removed from this reference because the WVHIN is now governed by a board of directors as a non-profit entity.

Response

The Department has reviewed this comment, believes the recommended modification would add clarity to the rule, and has modified the section accordingly.

Section 2 – Definitions.

Comment

2.50. The WVHIN recommends that the word "data" be stricken from the start of the definition and that the word "reporting" be substituted.

Response

The Department has reviewed this comment, believes the recommended modification would add clarity to the rule, and has modified the section accordingly.

Comment

2.54. The WVHIN has recommended the substitution of an updated definition for the WVHIN in this section.

Response

The Department has reviewed this comment, believes the recommended modification is more reflective of the organization and therefore has modified the rule accordingly.

Section 3 – Selection, Categorization, and Required Reporting.

Comment

3.5.a.1. It is recommended that “Category II” be changed to “Category III.”

Response

The Department has reviewed the comment and has modified the rule so that the appropriate category is reflected.

Comment

3.6.a.1. It is recommended that the text should be changed from “Category II” to “Category IV.”

Response

The Department has reviewed the comment and has modified the rule so that the appropriate category is reflected.

Comment

3.7.a.1. It is recommended that the text should be changed from “Category II” to “Category V.”

Response

The Department has reviewed the comment and has modified the rule so that the appropriate category is reflected.

Section 6. Other Reportable Events, Administration of Immunizations.

Comment

The WVHIN requests addition of its entity to which the administration of immunizations should be reported.

Response

The Department has reviewed the comment and affirms that the administration of vaccinations should be reported to the WVHIN as a health information exchange.

Section 7. Electronic Laboratory Reporting.

Comment

11.1. The central purpose of the modifications to 64CSR7 are to incorporate the requirement that laboratories report electronically to the Bureau for Public Health (the “Bureau”), and therefore permissive language around this requirement should be replaced with compulsory language.

Response

The Department has reviewed this comment and intends electronic reporting by laboratories to be compulsory and has therefore replaced permissive language with compulsory language and has reworked all of the language regarding laboratory reporting to make this more clear.

Section 12. Syndromic Surveillance.

Comment

12.2. The WVIN is serving as a mechanism for the reporting of syndromic surveillance to the Bureau and requests the enumeration of its organization in the section.

Response

The Department has reviewed this comment and believes that enumeration of the WVIN is unnecessary and therefore no change was made to the rule in response to this comment.



August 3, 2020

Ms. April L. Robertson
General Counsel
Department of Health and Human Resources
State of West Virginia
One Davis Square, Suite 100 East
Charleston, WV 25301

Dear Ms. Robertson,

On behalf of Quest Diagnostics, thank you for the opportunity to provide the following comments on title-series 64-07 establishing procedures governing the reporting of certain diseases and conditions, health events, and clusters of outbreaks of diseases to the Bureau of Public Health. As you may know, Quest Diagnostics is the world's leading provider of diagnostic information services. We are proud of our presence in the State of West Virginia, which includes approximately 67 employees and 1 patient service center. With our infrastructure in West Virginia, we service over 1,814 physicians and 16 hospitals.

Quest Diagnostics is at the forefront of the response to COVID-19 since we launched our first lab-developed COVID-19 molecular test on Monday, March 9. Since that time, Quest's testing capacity increased dramatically to perform over 150,000 COVID-19 molecular tests per day nationwide. In April, Quest entered the next phase of its response to the COVID-19 pandemic by rolling out antibody testing, which may indicate that a person has been exposed to the virus and may mean that the person has mounted an immune response. We are currently able to conduct more than 200,000 antibody tests per day through various specimen collection sites.

While we applaud the state's desire to establish stronger guidelines in reporting public health data, we caution that imposing additional reporting requirements will create a strain on our reporting system that will delay the delivery of critical testing results to our clients. As you know, clinical laboratories throughout the county, like Quest, are facing a high surge in demand for COVID-19 testing and are focused on ramping up capacity. This rule, as written, will require us to divert critical resources that will have a direct impact to patients in West Virginia.

We thank you for your leadership during this historic period. Please do not hesitate to contact me at (201) 602-3993 or David.M.Reiner@questdiagnostics.com if you have any questions or would like additional information.

Sincerely,

David M. Reiner

David M. Reiner
Sr. Director, State Government Affairs



VIA EMAIL

August 3, 2020

April L. Robertson
One Davis Square, Suite 100 East
Charleston, WV 25301
Email: april.l.robertson@wv.gov

**Re: West Virginia Health Information Network, Inc.'s Comments to the Bureau
for Public Health's Amendments to the Reportable Diseases, Events and
Conditions Legislative Rule**

Dear Ms. Robertson,

On behalf of the West Virginia Health Information Network, Inc. ("WVHIN"), please accept our comments on the proposed amendments to the Reportable Diseases, Events, and Conditions Legislative Rule, 64 C.S.R. 7 ("Rule"), issued for public review and input by the West Virginia Bureau for Public Health ("BPH") on July 2, 2020.

Reporting of disease conditions enables public health officials to recognize trends in diseases and to intervene in outbreak or epidemic situations. By collecting disease information reported by clinical partners and studying the trends, BPH can identify community-wide problems and implement preventative measures to maintain the health and safety of the citizens of West Virginia.

The WVHIN fully supports BPH's goal to make all reportable diseases, events, and conditions reportable via electronic means. Providing results via electronic exchange will provide BPH with real-time results in a specified format which provides needed flexibility and efficiency to address disease outbreaks and conditions. The WVHIN currently provides reporting to BPH and supports the amendments proposed to the Rule. Such amendments promote secure, integrated sharing of clinical information among numerous stakeholders, including clinical partners and BPH, through health information exchange. Reporting through the WVHIN will improve the efficiency and quality of public health reporting, facilitate public health investigation, improve emergency response, and enable public health to timely communicate information to the clinical community.

The WVHIN's comments and suggestions pertaining to each section of the amendments to the Rule are detailed below.

1. § 64-7-1. General. Section 1.6. Applicability.

- The WVHIN recognizes that it is referenced in Section 1.6 of the Rule, and assumes that reference is made in recognition of the WVHIN's defined role as a reporting mechanism on behalf of the BPH. The current language refers to the "administrators of the West Virginia Health Information Network (WVHIN)." The WVHIN requests that "administrators of" be removed from this reference to the WVHIN. Now that the WVHIN is a private, non-profit corporation, it operates as a separate entity with its own governing board of directors, it is no longer necessary to reference the WVHIN's administrators.

2. § 64-7-2 Definitions.

- The definition of "Validated Submitter" as set forth in 2.50 begins with: "a laboratory whose transmission of electronic laboratory data..." The WVHIN recommends that the word "data" be stricken from the start of the definition and that the word "reporting" be inserted. It would read as follows: "a laboratory whose transmission of electronic laboratory reporting..." This is recommended as "electronic laboratory reporting" is a defined term and it includes the submission of laboratory data within the definition.
- The definition of the WVHIN set forth in Section 2.54 of the Definitions needs revision. The WVHIN recommends the following definition to replace the current 2.54:

2.54 WVHIN-West Virginia Health Information Network, Inc.—A private, non-profit organization operating a statewide health information exchange to facilitate access to and retrieval of electronic protected health information between clinical partners and the Bureau via HL7 Messaging standards through electronic automated reporting.

3. 3.5 Category III. Reportable Diseases and Conditions.

- In Section 3.5.a.1 the added language needs revised from "Category II" to "Category III" diseases or conditions.

4. 3.6 Category IV. Reportable Diseases and Conditions.

- Section 3.6.a.1 the added language needs revised from "Category II" to "Category IV" disease or conditions.

5. 3.7 Category V reportable Diseases and Conditions.

- Section 3.7.a.1 the added language needs revised from "Category II" to "Category V" disease or conditions.

6. 64-7-6. Other Reportable Events. Administration of Immunizations.

- The WVHIN currently serves as a mechanism by which required reporters submit immunizations to the West Virginia Statewide Immunization Information System ("WVSIIS"). The WVHIN respectfully requests to be added by reference in this Section as a means by which those persons subject to and required to report immunizations under this Section may meet their electronic reporting obligations to the WVSIIS.

The WVHIN proposes the following underlined language be added to Section 6.2:

WVSIIS is an electronic reporting system. The following persons shall report immunizations administered to WVSIIS or through the WVHIN, as required by this rule;

7. §64-7-11. Electronic Laboratory Reporting.

- The WVHIN seeks clarification on the second sentence in Section 11.1 which states:

When the laboratory is designated as a validated submitter by the Commissioner the laboratory may substitute electronic reporting to the WVHIN or WVEDSS through HL-7 in real time for the required paper reporting.

The WVHIN recommends replacing the word "may" with the word "shall" as BPH's proposed amendments suggest that electronic submission will be required once the Rule is active.

8. §64-7-12. Syndromic Surveillance.


- The WVHIN is currently serving as a mechanism by which required reporters may provide syndromic surveillance electronically to BPH. The WVHIN respectfully requests that it be added to this Section by reference as a conduit by which clinical providers and other required reporters, as applicable, electronically report syndromic surveillance data.

The WVHIN proposes that the underlined language be added to Section 12.2:

When syndromic surveillance system is determined to be functional by the Commissioner, emergency rooms and urgent care facilities in the state shall report through the WVHIN daily all data elements for each registered patient visit as required by the Commissioner.

The WWHIN greatly appreciates the opportunity to offer comments and suggestions to the Rule. Like BPH, the WWHIN looks forward to aiding public health architecture by serving as the electronic conduit through which real-time electronic reporting of required diseases, events, and conditions will ultimately be provided to designated BPH officials.

Sincerely,

A handwritten signature in cursive script that reads "Sonia D. Chambers". The signature is written in black ink and is positioned above the printed name and title.

Sonia Chambers
Executive Director